

REMARKS

Applicants respectfully request further examination and reconsideration in view of the above amendment and the arguments set forth fully below. In the Office Action mailed September 11, 2006, claims 1-4, 6, 7, 9-15 and 17-24 have been rejected. In response, the Applicants have submitted the following remarks, and amended claim 1. Accordingly, claims 1-4, 6-7, 9-15 and 17-24 are still pending. Favorable reconsideration is respectfully requested in view of the amended claim and remarks below.

Rejections Under 35 U.S.C. §103

Claims 1-4, 6, 9-14 and 17-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,876,351 to Rohde (hereinafter Rohde) in view of U.S. Patent No. 6,238,338 to DeLuca et al. (hereinafter DeLuca), and further in view of U.S. Patent No. 5,967,994 to Wang (hereinafter Wang). The Applicants respectfully renew their arguments to this rejection and include the following additional arguments with respect to Rohde.

As stated previously, Rohde teaches a portable modular diagnostic medical device having an interchangeable cartridge system such that the functionality of the device to execute diagnostic medical function such as monitoring ECGs can be utilized and interchanged. The Applicants respectfully submit, and the Examiner would likely agree, that the preferred embodiment of the Rohde invention includes a portable modular diagnostic medical device having a cartridge for monitoring electrocardiograms in a patient. Throughout the Rhode reference, including the Rhode sections cited by the Examiner, it is taught that the Rohde reference in a preferred embodiment simply collects and displays ECGs of a patient on the screen of the modular device. Furthermore, throughout the Rhode reference, particularly the sections cited by the Examiner, it is mentioned that different medical functionality or diagnostic medical functions can be provided and utilized with the modular diagnostic medical device by plugging in additional cartridges into the device. The Rohde reference makes several mentions of

expanding the device to perform different diagnostic medical functions by merely switching the cartridge. However, the Rohde reference provides the lone example of an alternative diagnostic medical function as QRS detection, which as one skilled in the art would recognize, is a basic ECG analysis procedure (Rohde, column 13, lines 23-24). The Rhode reference provides no further teachings of other diagnostic medical functions that could be performed by switching the cartridge in the modular device. Furthermore, the Rohde reference provides no evidence or teaching that the device taught in Rohde can perform any more complicated procedure than monitoring of ECGs, or providing a basic analysis of the ECG as QRS detection.

In contrast to the teachings of Rohde the method and apparatus for analyzing a physiological waveform of the present invention includes the detection of cyclic artifacts and the selection of a lead based on the lack of artifacts. In short, the method and apparatus of the present invention executes a much more complicated diagnostic medical function in detecting cyclic artifacts and selecting a lead based on the lack of artifacts as is evidenced in Figures 6-9 of the present invention. As stated previously, the limited teachings of Rohde to include monitoring of ECGs and QRS detection do not provide sufficient teaching that the modular device in Rohde is capable of performing nor make obvious the ability to detect cyclic artifacts and select the lead based on the lack of artifacts. Therefore, the Applicants respectfully submit that the Rohde reference does not teach nor make obvious such functionality.

Wang teaches a method and system for characterizing the quality of signals inductive of heart function, wherein the signals in Wang are combined, and analyzed for noise quality. However, Wang does not teach an instrumentation amplifier that is configured to filter the ECG signals, combine the signals to generate a multi-lead ECG, and an analog-digital converter, that allows the multi-lead ECG to be converted to a digital signal and analyzed as a single digital signal for cyclic artifact.

DeLuca teaches a bio-signal monitoring system and method which includes an analog to digital converter. While the DeLuca reference teaches the ability to convert an

ECG signal to a digital signal, it fails to teach converting a multi-lead ECG signal into a multi-lead digital ECG signal for analysis to detect cyclic artifact. Therefore, even if combined, the references do not teach, nor make obvious the method and apparatus of the present invention as described and claimed.

The independent claim 1 is directed to a medical device for acquiring and analyzing a multi-lead electrocardiogram comprising an input terminal for connection to a patient to acquire multi-lead ECG signals from the patients, an instrumentation amplifier connected to the input terminal to filter the ECG signals and combine the signals to generate a multi-lead ECG, an analysis module including a processor and software for operating the processor to detect cyclic artifact in the multi-lead ECG and select a lead for analysis based on a lack of cyclic artifact in that lead, and an analog to digital converter connected between the instrumentation amplifier and the analysis module, wherein the multi-lead ECG generated by the instrumentation amplifier is an analog multi-lead ECG, where the analog to digital converter converts an analog multi-lead ECG to a digital multi-lead ECG and wherein the analysis module detects cyclic artifact in the digital multi-lead ECG. As discussed above, neither Rohde, Wang, DeLuca nor their combination teach analyzing a digital multi-lead ECG signal for cyclic artifact. For at least these reasons, the independent claim 1 is allowable over the teachings of Rohde, Wang, DeLuca and their combination. For the same reasons, the Applicants respectfully submit that the independent claims 9 and 17 are also allowable over the teachings of Rohde, Wang, DeLuca and their combination.

Claims 2-4, 6, 10-14 and 18-23 are dependent upon the independent claims 1, 9, and 17. As discussed above, the independent claims 1, 9, and 17 are allowable over the teachings of Rohde, Wang, DeLuca and their combination. Accordingly, claims 2-4, 6, 10-14 and 18-23 are also allowable as being dependent upon an allowable base claim.

Claims 7, 15 and 24 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rohde, DeLuca, and Wang, and further in view of U.S. Patent No. 6,119,035 also to Wang. Claims 7, 15 and 24 are dependent upon the independent claims

Application No. 10/757,174
Response Dated December 11, 2006
Reply to Office Action of September 11, 2006

1, 9, and 17. As discussed above, the independent claims 1, 9 and 17 are allowable over the teachings of Rohde, Wang, DeLuca and their combination. Accordingly, claims 7, 15 and 24 are also allowable as being dependent upon an allowable base claim.

Claim Objections

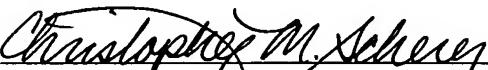
Claim 1 has been objected to because there is a typographical error in line 3. The Applicants have remedied this error and an additional error in line 1 by the above amendment. Therefore, the Applicants respectfully request that the Examiner withdraw this objection to claim 1.

For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By



Christopher M. Scherer

Reg. No. 50,655

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
Telephone: (414) 271-7590
Facsimile: (414) 271-5770